Claims

1. A salt of topiramate, or a polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

2. The salt of claim 1 wherein the salt is topiramate sodium, topiramate lithium, or topiramate potassium.

3. Topiramate sodium, or a polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

4. Topiramate sodium trihydrate, or a polymorph thereof.

5. The topiramate sodium trihydrate of claim 4, or a polymorph thereof, which is a fine lathe-like crystalline solid.

6. A salt of topiramate which has unique powder X-ray diffraction peaks at approximately 4.5, 13.6, and 19.1 degrees 2-Theta.

7. A form of topiramate which has an aqueous solubility greater than about 10 mg/ml at 25° C.

8. The form of claim 7 which has an aqueous solubility greater than about 50 mg/ml at 25° C.

9. The form of claim 8 which has an aqueous solubility greater than about 100 mg/ml at 25° C.

10. The form of claim 7 wherein the form is a salt form.

11. A co-crystal or complex of topiramate.

12. The co-crystal or complex of claim 11, wherein said co-crystal or complex is a co-crystal or complex of caffeine and topiramate.

13. A pharmaceutical composition comprising a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof, and a pharmaceutically acceptable excipient or diluent.

14. The pharmaceutical composition of claim 13 wherein the pharmaceutically acceptable salt of topiramate is topiramate sodium, topiramate lithium, or topiramate potassium.

15. The pharmaceutical composition of claim 14 wherein the pharmaceutically acceptable salt is topiramate sodium.

16. The pharmaceutical composition of claim 15 in which the topiramate sodium is topiramate sodium trihydrate, or a polymorph thereof.

17. A pharmaceutical composition comprising a co-crystal or complex of topiramate and a pharmaceutically acceptable excipient or diluent.

18. The pharmaceutical composition of claim 17 wherein said co-crystal or complex is a co-crystal or complex of caffeine and topiramate.

19. A pharmaceutical unit dosage form comprising a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof, and an excipient.

20. The pharmaceutical unit dosage form of claim 19 wherein the pharmaceutically acceptable salt of topiramate is topiramate sodium, topiramate lithium, or topiramate potassium.

21. The pharmaceutical unit dosage form of claim 20 wherein the pharmaceutically acceptable salt is topiramate sodium.

22. The pharmaceutical unit dosage form of claim 21 in which the topiramate sodium is topiramate sodium trihydrate, or a polymorph thereof.

23. The pharmaceutical unit form of claim 19 which is suitable for oral, mucosal, parenteral, or transdermal administration to a patient.

24. The pharmaceutical unit dosage form of claim 23 formulated for controlled release of the pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

25. The pharmaceutical unit dosage form of claim 24, wherein the controlled release occurs by osmosis.

26. A capsule comprising a salt of topiramate.

27. The capsule of claim 26, wherein said capsule is a gelcap.

28. A pharmaceutical unit dosage form comprising a co-crystal or complex of topiramate.

29. The pharmaceutical unit dosage form of claim 28 wherein said co-crystal or complex is a co-crystal or complex of caffeine and topiramate.

30. The pharmaceutical unit form of claim 28 which is suitable for oral, mucosal, parenteral, or transdermal administration to a patient.

31. The pharmaceutical unit dosage form of claim 30 formulated for controlled release of the co-crystal.

32. The pharmaceutical unit dosage form of claim 31, wherein the dosage form is a matrix, erodible, coated, or osmotic controlled release dosage form.

33. The pharmaceutical unit dosage form of claim 32 wherein the controlled release occurs by osmosis.

34. A method of treating or preventing seizures in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

35. A method of treating or preventing seizures in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

36. The method of claim 34 wherein the seizure is a partial seizure or a generalized seizure.

37. The method of claim 34 which further comprises the adjunctive administration of another anticonvulsant.

38. The method of claim 37 wherein the anticonvulsant is carbamazepine, phenytoin, ethotiagabine, valproic acid, ethosuximide, felbamate, gabapentin, lamotrigine, levetiracetam, or oxcarbazepine.

39. A method for treating or preventing tremors in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective

amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

40. A method for treating or preventing tremors in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

41. A method of treating migraine in a human patient which comprises administering to a patient in need of such treatment a therapeutically effective amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

42. A method of treating migraine in a human patient which comprises administering to a patient in need of such treatment a therapeutically effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

43. A method of reducing the frequency or severity of migraine in a human patient which comprises administering to the patient in need thereof an effective amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

44. A method of reducing the frequency or severity of migraine in a human patient which comprises administering to the patient in need thereof an effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

45. A method of treating or preventing neuropathic pain in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

46. A method of treating or preventing neuropathic pain in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

47. The method of claim 45 wherein the neuropathic pain is neuralgia.

48. A method treating or preventing a cerebral function disorder which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

49. A method treating or preventing a cerebral function disorder which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

50. The method of claim 48 wherein the cerebral function disorder is Alzheimer's disease.

51. The method of claim 48 wherein the cerebral function disorder is Parkinson's disease.

52. A method of treating or preventing obesity or weight gain in a patient which comprises administering to a patient in need of such treatment a therapeutically or prophylactically effective amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

53. A method of treating or preventing obesity or weight gain in a patient which comprises administering to a patient in need of such treatment a therapeutically of prophylactically effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

54. A method of treating or preventing affective disorders in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

55. A method of treating or preventing affective disorders in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

56. The method of claim 54 wherein the affective disorder is a manic condition, an acute mania, manic rapid cycling, bipolar mood disorders or condition, manic-depressive bipolar disorder, mood stabilization, post-traumatic stress disorder, depression, an anxiety disorder, attention deficit disorder, attention deficit disorder with hyperactivity, compulsive or obsessive-compulsive disorder, narcolepsy, premenstrual syndrome, chronic fatigue syndrome, seasonal affective disorder, substance abuse or addiction, or nicotine addiction or craving.

57. A method of treating or preventing cluster headache in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

58. A method of treating or preventing cluster headache in a patient which comprises administering to a patient in need of such treatment or prevention a therapeutically or

prophylactically effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

59. A method of eliciting smoking cessation which comprises administering to a patient in need thereof a therapeutically effective amount of a pharmaceutically acceptable salt of topiramate, or a pharmaceutically acceptable polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

60. A method of eliciting smoking cessation which comprises administering to a patient in need thereof a therapeutically effective amount of a pharmaceutically acceptable co-crystal or complex of topiramate.

61. The method of claim 35 wherein said co-crystal or complex is a co-crystal or complex of topiramate and caffeine, N-methyl pyrrolidine, nicotine, or nicotinamide.

62. A pharmaceutical dosage form which comprises: a wall defining a cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the exit orifice and in fluid communication with the semipermeable portion of the wall; a dry or substantially dry state drug layer located within the cavity adjacent the exit orifice and in direct or indirect contacting relationship with the expandable layer; and a flow-promoting layer interposed between the inner surface of the wall and at least the external surface of the drug layer located within the cavity, wherein the drug layer comprises a salt of topiramate, or a polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

63. A pharmaceutical dosage form which comprises: a wall defining a cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the exit orifice and in fluid communication with the semipermeable portion of the wall; a drug layer located within the cavity adjacent the exit orifice and in direct or indirect contacting relationship with the

expandable layer; the drug layer comprising a liquid, active agent formulation absorbed in porous particles, the porous particles being adapted to resist compaction forces sufficient to form a compacted drug layer without significant exudation of the liquid, active agent formulation, the dosage form optionally having a placebo layer between the exit orifice and the drug layer, wherein the active agent formulation comprises a salt of topiramate, or a polymorph, solvate, hydrate, dehydrate, co-crystal, anhydrous, or amorphous form thereof.

64. The dosage form of claim 62 wherein the salt of topiramate is a lithium potassium, or sodium salt.

65. The dosage form of claim 64 wherein the salt of topiramate is topiramate sodium trihydrate.

66. A pharmaceutical dosage form which comprises: a wall defining a cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the exit orifice and in fluid communication with the semipermeable portion of the wall; a dry or substantially dry state drug layer located within the cavity adjacent the exit orifice and in direct or indirect contacting relationship with the expandable layer; and a flow-promoting layer interposed between the inner surface of the wall and at least the external surface of the drug layer located within the cavity, wherein the drug layer comprises a co-crystal or complex of topiramate.

67. A pharmaceutical dosage form which comprises: a wall defining a cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the exit orifice and in fluid communication with the semipermeable portion of the wall; a drug layer located within the cavity adjacent the exit orifice and in direct or indirect contacting relationship with the expandable layer; the drug layer comprising a liquid, active agent formulation absorbed in porous particles, the porous particles being adapted to resist compaction forces sufficient to form a compacted drug layer without significant exudation of the liquid, active agent formulation, the

dosage form optionally having a placebo layer between the exit orifice and the drug layer, wherein the active agent formulation comprises a co-crystal or complex of topiramate.

68. The dosage form of claim 66 wherein the co-crystal or complex is a co-crystal or complex of topiramate and caffeine, N-methyl pyrrolidine, nicotine, or nicotinamide.